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Original Research

Self-Monitoring of Blood Glucose Levels: Evaluating the Impact of a Policy of Quantity Limits on Test-Strip Use and Costs



Tara Gomes MHSc ^{a,b,c,d,*}, Diana Martins MSc ^b, Mina Tadrous PharmD, PhD ^{a,b,c},
J. Michael Paterson MSc ^{b,d,e,f}, Baiju R. Shah MD, PhD ^{b,d,g,h}, David N. Juurlink MD, PhD ^{b,d,g,h,i},
Samantha Singh BSc ^b, Muhammad M. Mamdani PharmD, MA, MPH ^{a,b,c,d,g,j}

^a Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Ontario, Canada^b The Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada^c Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario, Canada^d Institute for Health Policy, Management, and Evaluation, University of Toronto, Toronto, Ontario, Canada^e Department of Family Medicine, McMaster University, Hamilton, Ontario, Canada^f Centre for Evaluation of Medicines, St. Joseph's Healthcare, Hamilton, Ontario, Canada^g Department of Medicine, University of Toronto, Toronto, Ontario, Canada^h Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canadaⁱ Department of Pediatrics, University of Toronto, Toronto, Ontario, Canada^j Department of Medicine, St. Michael's Hospital, Toronto, Ontario, Canada

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ABSTRACT

Objectives: To evaluate the impact of new quantity limits for blood glucose test strips (BGTS) in August 2013 on utilization patterns and costs in the elderly population of Ontario, Canada.

Methods: We conducted a population-based, cross-sectional time series analysis of all individuals 65 years of age and older who received publically funded BGTSs between August 1, 2010, and July 31, 2015, in Ontario, Canada. The number of BGTSs dispensed and the associated costs were measured for 4 diabetes therapy subgroups—insulin, hypoglycemia-inducing oral agents, non-hypoglycemia-inducing oral agents, and no drug therapy—each month during the study period. We used interventional autoregressive integrated moving average (ARIMA) models to assess the impact of Ontario's policy change on test strip use and costs.

Results: In the course of the study period, 657,338,177 test strips were dispensed to elderly patients in Ontario, at a total cost of CAN\$482.3 million. Introduction of quantity limits was associated with significant reductions in the number of monthly strips dispensed and the associated costs ($p < 0.0001$). In the year following the policy's implementation, test strip use decreased by 22.2% compared with the prior year (from 145,232,024 test strips to 113,007,795 test strips, a net decrease of 32,224,229 strips), resulting in a 22.5% reduction in costs (from \$106.5 million to \$82.6 million, a net cost reduction of approximately \$24 million).

Conclusions: The introduction of quantity limits, aligned with guidance from the Canadian Diabetes Association, led to immediate significant reductions in BGTS dispensing and costs. More research is needed to assess the impact of this policy on patient outcomes.

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R É S U M É

Objectifs : Évaluer les répercussions des nouvelles restrictions quantitatives de bandelettes réactives pour la glycémie (BRG) d'août 2013 sur les tendances et les coûts d'utilisation chez la population âgée de l'Ontario, au Canada.

Méthodes : Nous avons mené une analyse transversale des séries chronologiques de tous les individus de 65 ans et plus qui ont reçu des BRG subventionnées par le gouvernement entre le 1^{er} août 2010 et le 31 juillet 2015, en Ontario, au Canada. Nous avons évalué le nombre de BRG distribuées et les coûts associés de 4 sous-groupes de traitement du diabète—insuline, agents oraux provoquant des hypoglycémies, agents oraux ne provoquant pas d'hypoglycémies et sans pharmacothérapie—tous les mois au cours de la période étudiée. Nous avons utilisé des modèles autorégressifs à moyennes mobiles intégrés (ARMMI) pour évaluer les répercussions des changements de politiques de l'Ontario sur l'utilisation et les coûts des bandelettes réactives.

Mots clés :
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* Address for correspondence: Tara Gomes, MHSc, Li Ka Shing Knowledge Institute of St. Michael's Hospital, 30 Bond Street, Toronto, Ontario M5B 1W8, Canada.

E-mail address: GomesT@smh.ca

Résultats : Au cours de la période étudiée, 657 338 177 bandelettes réactives ont été distribuées aux patients âgés de l'Ontario, soit un coût total de 482.3 M\$ CA. La mise en place des restrictions quantitatives était associée à des réductions significatives du nombre mensuel de bandelettes distribuées et des coûts associés ($p < 0.0001$). Dans l'année qui a suivi la mise en œuvre des politiques, l'utilisation des bandelettes réactives a diminué de 22.2% par rapport à l'année précédente (de 145 232 024 bandelettes réactives à 113 007 795 bandelettes réactives, soit une diminution nette de 32 224 229 bandelettes), ce qui a entraîné une réduction des coûts de 22.5 % (de 106.5 M\$ à 82.6 M\$, soit une réduction nette approximative des coûts de 24 M\$).

Conclusions : La mise en place des restrictions quantitatives, en conformité avec l'Association canadienne du diabète, a entraîné des réductions significatives immédiates dans la distribution des BRG et des coûts qui y sont associés. D'autres recherches sont nécessaires pour évaluer les répercussions de cette politique sur les résultats cliniques des patients.

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Introduction

The optimal use of self-monitoring of blood glucose (SMBG) by people with diabetes is an area of uncertainty, given the need to balance appropriate use affecting patient care and the potential for overuse and unnecessary healthcare costs (1–3). Indeed, a 2009 Canadian review suggested that in individuals with diabetes who do not use insulin, frequent testing may not offer any clinical benefit and may, in fact, cause increased anxiety (4,5). Moreover, the aggregate costs of blood glucose test strips (BGTs) can represent considerable cost burdens. Between 2010 and 2013, BGTs were consistently among the top 10 expenditures in the Ontario public drug formulary (6–8). One approach taken by public drug insurers has been the introduction of annual limits on the number of BGTs reimbursed. The aim of these policies is to provide patients with sufficient test strips for appropriate blood glucose monitoring while reducing the potential for overuse and unnecessary expense. Studies have suggested that the financial implications of such limits are considerable (9,10), with 5-year savings estimated to be approximately \$100 million and \$23 million in Ontario and British Columbia, Canada, respectively (11).

Following consultation with clinical experts and stakeholders, the Ontario public drug plan introduced quantity limits for BGTs in August 2013 that aligned with the guidance published by the Canadian Diabetes Association (3,12). The policy limits reimbursement to up to 3000 strips per year for insulin-treated patients, 400 strips per year for those treated with oral hypoglycemic agents (OHAs) that may cause hypoglycemia (such as sulfonylureas), and 200 strips per year for all other individuals with diabetes. Extra test strips are reimbursed if there is a clinical rationale for more frequent testing, such as drug interactions that impact blood glucose control, failing to meet glycemic targets for 3 or more months, or an occupation that requires strict avoidance of hypoglycemia (13).

As other drug insurers consider policy options for addressing the rising costs associated with BGTs, evaluations of the impact of Ontario's policy on utilization, costs and outcomes are needed. We report the findings of the first phase of an evaluation of Ontario's policy; the study assessed the impact of quantity limits on test strip utilization patterns and costs in Ontario by seniors.

Methods

We conducted a population-based, cross-sectional time series analysis of all individuals 65 years of age and older who received publicly funded BGTs between August 1, 2010, and July 31, 2015, in Ontario, Canada. This study was approved by the Research Ethics Board of Sunnybrook Health Sciences Centre, Toronto.

Cohort definition

We included all individuals 65 years of age and older who were dispensed BGTs reimbursed by the Ontario Public Drug Program

during the study period. Prescriptions were identified using the Ontario Drug Benefit database, which captures all reimbursed medications dispensed at Ontario retail pharmacies to individuals eligible for public drug coverage. Prescriptions with missing patient identifiers or age and those dispensed to individuals younger than 65 were excluded from the analysis.

Outcome definition

Each month, we determined the number of test strips dispensed to eligible patients and the associated public payer costs (product costs and dispensing fees, excluding deductibles). Costs were expressed in nominal Canadian dollars. Furthermore, we created 2 cohorts of patients using BGTs in the year prior to (July 1, 2012, to June 30, 2013) and following (August 1, 2013, to July 31, 2014) the implementation of Ontario's policy to compare patterns of utilization and costs in the prepolicy and postpolicy periods. We excluded the month immediately prior to implementation of the policy (July 2013) because of anomalous dispensing patterns suggestive of stockpiling by patients in anticipation of the policy. We allocated patients to 1 of 4 hierarchic and mutually exclusive groups on the basis of the diabetes treatment received in each period, as follows: those treated with insulin; those receiving hypoglycemia-inducing oral glucose-lowering drugs (sulfonylureas or repaglinide); those receiving non-hypoglycemia-inducing glucose-lowering drugs; and those not receiving diabetes medications. The total number of test strips dispensed, the average number of test strips dispensed per patient, and the proportion of individuals exceeding the Ontario quantity limits were identified and stratified by cohort (prepolicy vs. postpolicy) and diabetes therapy group. Finally, to assess whether patients were being prescribed insulin in order to access higher BGT quantity limits, we identified the total number of new insulin users in the year prior to and following the policy's implementation, as well as the number of new insulin users who received only 1 prescription for insulin in each time period.

Patients' characteristics

We used the Registered Persons Database to obtain demographic characteristics of individuals dispensed BGTs in the 1 year prior to and following the policy's implementation. The Canadian Institute for Health Information's Discharge Abstract Database was used to determine each individual's Charlson comorbidity index using hospitalization data over the past 3 years.

Statistical analysis

We used a Winters additive smoothing model to forecast BGT utilization patterns over our 2-year follow up based on trends observed in the 3 years prior to the policy's implementation (excluding July 2013 due to observed stockpiling). We used interventional autoregressive integrated moving average models to examine the impact of Ontario's quantity-limit policy (August 2013) on the

number of BGTSs dispensed to the elderly in Ontario. The effects of the policy were assessed using a step function in the model. We assessed the autocorrelation, partial autocorrelation and inverse autocorrelation correlograms for model parameter selection and appropriateness, stationarity using the augmented Dickey-Fuller test and autocorrelation using the Ljung-Box chi-square test. We used chi-square tests to compare the proportion of individuals exceeding the policy's quantity limits between the prepolicy and postpolicy cohorts. All analyses were performed at the Institute for Clinical Evaluative Sciences (www.ices.on.ca) using SAS software (SAS v. 9.3 and SAS EG 6.1; SAS Institute, Cary, North Carolina, USA) and using a type 1 error rate of 0.05 as the threshold for statistical significance.

Table 1

Characteristics of patients using blood glucose test strips in the 1 year preceding and following the policy's implementation

Characteristic	1 year prepolicy cohort n=324,689	1 year postpolicy cohort n=327,716
Age (mean ± SD)	74.5±7.2	74.6±7.2
Male sex (n, %)	163,279 (50.3%)	165,237 (50.4%)
Income quintile		
1	70 060 (21.6%)	70 359 (21.5%)
2	70 728 (21.8%)	71 303 (21.8%)
3	65 747 (20.2%)	66 342 (20.2%)
4	62 814 (19.3%)	63 853 (19.5%)
5	53 736 (16.5%)	54 170 (16.5%)
Missing	1604 (0.5%)	1689 (0.5%)
Rural		
No	280,030 (86.2%)	283,196 (86.4%)
Yes	44 271 (13.6%)	44 043 (13.4%)
Missing	388 (0.1%)	477 (0.1%)
Charlson morbidity index		
No hospitalization	219,033 (67.5%)	221,258 (67.5%)
0	12 043 (3.7%)	11 814 (3.6%)
1	24 780 (7.6%)	24 560 (7.5%)
2+	68 833 (21.2%)	70 084 (21.4%)

Results

Between August 2010 and July 2015, a total of 657,338,177 test strips were dispensed to elderly patients in the Ontario Public Drug Program, costing \$482.3 million. In July 2013, the month prior to the implementation of Ontario's quantity-limit policy, BGTS utilization increased by 38% to 16,672,407 test strips dispensed (costing \$12.6 million) from a monthly average of 12,075,188 test strips (average cost \$9.1 million) in the 6 months prior. Patients' characteristics and comorbidities were similar in the year prior to and following the policy's implementation (Table 1). On average, BGTS users were 75 years old, and approximately half were male.

We fit an interventional autoregressive integrated moving average (ARIMA) model (8, 1, 0) to the data over the entire study period (August 2010 to July 2015), with an R-square of 0.74. Using a step function in the ARIMA model to measure the impact of Ontario's policy, we found a significant, sustained reduction in the number of test strips dispensed ($p<0.0001$) (Figure 1). There were 32,224,229 fewer BGTS dispensed in the year following the policy's implementation (113,007,795 strips, August 2013 to July 2014) compared to the prior year (145,232,024 strips, July 2012 to June 2013), resulting in a 1-year savings of \$23.9 million (from \$106.5 million to \$82.6 million). By the end of the study period (July 2015), 9,262,553 test strips were dispensed monthly to elderly drug beneficiaries in Ontario at a cost of \$7.0 million (compared with 11,829,943 test strips monthly at a cost of \$8.9 million in June 2013, prior to the policy's implementation).

In the year following the implementation of Ontario's policy, several shifts in test strip utilization emerged (Table 2). For example, the number of individuals dispensed BGTS fell among those treated with no drug therapy and hypoglycemia-inducing OHAs and rose among those treated with non-hypoglycemia-inducing OHAs and insulin. Furthermore, the number of BGTSs dispensed fell 44.1% (from



Figure 1. Trends in blood glucose test strip utilization and costs in Ontario: August 2010 to July 2015. Ontario policy introduced in August 2013. Elevated dispensing in July 2013 is indicative of stockpiling prior to policy implementation.

Table 2

Blood glucose test strip utilization among prepolicy and postpolicy test strip users, by diabetes therapy group

Diabetes therapy group	Patients n (%)	Blood glucose test strip prescriptions n (%)	Blood glucose test strips dispensed n (%)	No. prescriptions/ patient Mean (SD)	No. blood glucose test strips/patient Mean (SD)	Average cost/patient Mean (SD)
1-year prepolicy						
Overall	324,689	1,075,665	145,232,024	3.3 (2.9)	447 (426)	\$328 (\$317)
No drug therapy	50 873 (15.7%)	107,768 (10.0%)	13,056,735 (9.0%)	2.1 (1.8)	257 (255)	\$182 (\$190)
Non-hypoglycemia-causing OHAs	102,935 (31.7%)	269,170 (25.0%)	33,554,480 (23.1%)	2.6 (2.2)	326 (290)	\$237 (\$217)
Hypoglycemia-causing OHAs	85 081 (26.2%)	265,617 (24.7%)	34,423,490 (23.7%)	3.1 (2.5)	405 (347)	\$298 (\$360)
Insulin	85 800 (26.4%)	433,110 (40.3%)	64,197,319 (44.2%)	5.1 (3.6)	748 (544)	\$554 (\$401)
Year 1 postpolicy						
Overall	327,716	875,465	113,007,795	2.7 (2.6)	345 (380)	\$252 (\$283)
No drug therapy	48 723 (14.9%)	69 127 (7.9%)	7,302,103 (6.5%)	1.4 (0.6)	150 (68)	\$102 (\$54)
Non-hypoglycemia-causing OHAs	105,469 (32.2%)	164,439 (18.8%)	17,724,002 (15.7%)	1.6 (0.7)	168 (70)	\$119 (\$55)
Hypoglycemia-causing OHAs	81 001 (24.7%)	180,196 (20.6%)	20,665,543 (18.3%)	2.2 (1.2)	255 (132)	\$187 (\$99)
Insulin	92 523 (28.2%)	461,703 (52.7%)	67,316,147 (59.6%)	5.0 (3.7)	728 (528)	\$540 (\$390)
Year 2 postpolicy						
Overall	328,870	886,942	112,469,184	2.7 (2.7)	342 (392)	\$252 (\$292)
No drug therapy	46 291 (14.1%)	62 815 (7.1%)	6,492,722 (5.8%)	1.4 (0.6)	140 (67)	\$98 (\$54)
Non-hypoglycemia-causing OHAs	106,019 (32.2%)	157,923 (17.8%)	16,558,652 (14.7%)	1.5 (0.7)	156 (69)	\$113 (\$54)
Hypoglycemia-causing OHAs	78 344 (23.8%)	168,812 (19.0%)	18,494,009 (16.4%)	2.2 (1.2)	236 (130)	\$174 (\$98)
Insulin	98 216 (29.9%)	497,392 (56.1%)	70,923,801 (63.1%)	5.1 (3.8)	722 (533)	\$537 (\$394)

OHA, oral hypoglycemic agents.

Table 3

Prevalence of patients exceeding blood glucose test strip quantity limits pre- and postpolicy, by diabetes therapy group

Diabetes drug therapy group	Prepolicy			Year 1 postpolicy			p value ^a	Year 2 postpolicy			p value ^b
	No. patients	Patients exceeding quantity limit		No. patients	Patients exceeding quantity limit			No. patients	Patients exceeding quantity limit		
		n	%		n	%			n	%	
No drug therapy	50 873	17 356	34.1%	48 723	3128	6.4%	<.0001	46 291	2290	5.0%	<.0001
Non-hypoglycemia-causing OHA	102,935	49 600	48.2%	105,469	10 584	10.0%	<.0001	106,019	8186	7.7%	<.0001
Hypoglycemia-causing OHA	85 081	26 685	31.4%	81 001	4390	5.4%	<.0001	78 344	3820	4.9%	<.0001
Insulin	85 800	273	0.3%	92 523	59	0.1%	<.0001	98 216	101	0.1%	<.0001

OHA, oral hypoglycemic agents.

^a Chi-square test of proportions for prepolicy vs. year 1 postpolicy.^b Chi-square test of proportions for prepolicy vs. year 2 postpolicy.

13.1 to 7.3 million strips), 47.2% (from 33.6 to 17.7 million strips) and 40.0% (from 34.4 to 20.7 million strips) among those treated with no drug therapy, non-hypoglycemia-causing OHAs and hypoglycemia-causing OHAs, respectively. In contrast, the number of test strips dispensed to individuals treated with insulin rose 4.9% (from 64.2 million to 67.3 million test strips). Between August 1, 2013, and July 31, 2014, 59.6% of all BGTs were dispensed to individuals treated with insulin (compared to 44.2% in the prior year). These trends continued into the second year following the policy intervention, with 63.1% of BGTs being dispensed to individuals treated with insulin.

The average annual rate of BGTs use and costs per person decreased across all diabetes therapy groups (Table 2). This reduction was most apparent among non-insulin treated patients, for whom the average annual rate of BGTs use dropped by more than 100 test strips per person, and average annual costs were lowered by between \$80 and \$118 per person (Table 2). Among those treated with insulin, on average, 20 fewer test strips were dispensed annually per person following the introduction of the policy (from 748 to 728 test strips per patient, annually), leading to a minimal shift in annual costs (\$14 savings per person, from \$554 to \$540 per person, annually). This led to a significant shift in the prevalence of individuals exceeding the quantity limits introduced by the government ($p < 0.0001$) (Table 3). In the year following the policy's introduction, 6.4% of individuals receiving no diabetes drug therapy, 10.0% of those treated with non-hypoglycemia-inducing OHAs and 5.4% of those treated with hypoglycemia-inducing OHAs received BGTs quantities that exceeded the policy's limits (compared to 34.1%, 48.2% and 31.4% in the prior year, respectively). This was even lower in

the second year following the policy's implementation, ranging from 4.9% to 7.7%. Among those treated with insulin, only 59 patients (0.06%) and 101 patients (0.1%) exceeded the quantity limit of 3000 BGTs in the 1 and 2 years following the policy implementation, respectively, compared to 273 (0.3%) in the prior year.

In our investigation of insulin use, we found that there were slightly more individuals initiating insulin in the year following the policy's implementation compared to the year preceding it ($n = 15\,706$, 4.8% prepolicy vs. $n = 16\,206$, 5.0% postpolicy; $p = 0.04$). Among those initiating insulin in each time period, a slightly higher proportion received only 1 prescription in the year following the policy's implementation ($n = 2712$, 16.7%) compared with the year preceding policy implementation ($n = 2382$, 15.2%; $p = 0.0001$). However, these shifts did not persist into the second year following the policy's implementation ($p = 0.93$ and $p = 0.06$, respectively).

Discussion

In this large, population-based study, we found that the introduction of a policy designed to restrict the quantity of BGTs dispensed to elderly individuals with diabetes in a way that aligned with clinical guidance led to a considerable and sustained shift in the dispensing patterns of these products. Specifically, the policy led to almost \$24 million in savings over the subsequent year, with the majority of the decreased use occurring among those individuals with diabetes not treated with insulin.

Our findings regarding shifts in diabetes therapy groups after the policy implementation warrant further discussion. In particular, we

found that fewer people were treated with hypoglycemia-inducing OHAs, while more were treated with insulin. Furthermore, there was a significantly increased prevalence of individuals receiving just 1 prescription for insulin in the year following the policy implementation; however, this did not persist into the second year of follow up. Although these patterns suggest that prescribers may have shifted their patterns of diabetes therapy prescribing to subvert quantity limits for BGTSs, overall this represented a small number of patients (330 additional new insulin users who were dispensed only 1 insulin prescription).

Following Ontario's implementation of quantity limits in 2013, several other public drug funders have followed suit, including both British Columbia's provincial drug program and Health Canada's Non-Insured Health Benefits Program (14,15). This study provides useful information for other jurisdictions regarding the potential cost savings that might be realized following the introduction of these policies (~22% lower costs in year after vs. year prior to policy). Furthermore, other drug programs considering similar policies should take note of our findings of increased BGTS dispensing in the month prior to the policy implementation because it is likely that this increased dispensing activity will occur elsewhere in the time between the announcement of a policy of restricted access and full policy implementation.

This study has many strengths, including its population-based design and long study period (including 2 years of follow up after the implementation of the quantity-limit policy). However, several limitations merit emphasis. First, we cannot measure the impact of the escalated BGTS dispensing in the month prior to policy implementation on subsequent BGTS needs in the following year. As a result, it is possible that some individuals were testing more frequently than suggested by their subsequent prescription claims, given their accumulation of BGTS prior to the policy's implementation. However, we did not observe an increase in BGTS dispensing in the second year following the quantity-limit policy's implementation, suggesting that the observed reductions in utilization and costs can be expected to be maintained in the future. Second, we do not have access to prescriptions paid for through private drug insurers or cash. Therefore, it is possible that some individuals were supplementing their access to BGTSs through other means. Third, it is likely that many of those individuals identified as having exceeded the quantity limits postpolicy in Table 3 met the policy's criteria for extra test strips. However, we were unable to determine whether these individuals truly met these conditions (i.e. drug interactions, occupational hazards) due to limitations in our data and so cannot determine whether this additional use was appropriate. Finally, we do not know whether reduced access to BGTSs has led to changes in clinical outcomes for those impacted by this policy in Ontario. Future research is needed to assess these outcomes once data becomes available.

Conclusions

This large, population-based analysis suggests that the implementation of an SMBG quantity limit policy that aligns with current evidence can lead to considerable cost savings and that exceptions to these limits occur in less than 10% of the population. As more data become available concerning clinical outcomes, studies are needed to evaluate the impact of BGTS quantity limits on patients' outcomes.

Conflict of interest

Dr. Muhammad M. Mamdani has received honoraria from Boehringer Ingelheim, Pfizer, Sanofi, Bristol-Myers Squibb, Astra-Zeneca, GlaxoSmithKline, Novo-Nordisk, Eli Lilly, Merck and Bayer. All other authors report no conflicts of interest.

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Author Contributions

TG, DM, MT, JMP, BRS, DNJ, SS and MMM conceived and designed the study; TG, DM and SS acquired the data; TG, DM, MT, JMP, SS, DNJ and MMM analyzed and interpreted the data; TG, DM, MT, JMP, BRS, DNJ, SS and MMM drafted the article or revised it critically for intellectual content; TG, DM, MT, JMP, BRS, DNJ, SS and MMM gave final approval of the version to be published.

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